

REMARKS

Claims 10, 13, 15-20, 22-25, 28, and 29 were pending in this application. Claims 19, 20, 22-25, 28, and 29 were allowed. Claims 10, 13, and 18 were rejected and claims 15-17 were objected to. In this Response, new claims 34-43 have been added. No claims have been amended or cancelled. No new matter has been added. Consequently, claims 10, 13, 15-20, 22-25, 28, 29, and 34-43 are now under consideration.

Amendment and cancellation of a claim is made without prejudice and is not to be construed as a dedication to the public of any subject matter. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned “**VERSION WITH MARKINGS TO SHOW CHANGES MADE**”.

Rejections under 35 U.S.C. §102(e)

Claims 10, 13, and 18

Claims 10, 13, and 18 stand rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 5,597,897 to Ron *et al.* (“Ron”). In support of this rejection, the Office Action states that “Ron et al teach a composition comprising an active and a copolymer of Lactic and glycolic acids (Abstract). Particulates are specified (column 2, lines 25-33). Hydroxypropylmethyl cellulose at 0.5-20% is specified (column 5, lines 13-30). Claims 10, 13, 18 are rejected” (*see* Office Action, page 2).

Applicants disagree with this rejection. To be anticipatory, a reference must teach each and every element of the claimed invention. Claim 10, from which claims 13 and 18 depend, recites an implant comprising three components (a biodegradable polymer, an active agent, and a release modulator) and further recites “wherein said implant is an *anhydrous solid* structure” (emphasis added). Ron fails to teach or disclose a three component implant that is anhydrous and a solid structure, as required by the pending claims.

First, Ron fails to disclose a three component implant that is anhydrous. In fact, Ron describes that his implants are prepared by mixing various components, together with water, *see* Example 4 (noting that water was added to form a malleable implant). The water is not later removed from the implant (i.e., before implantation), and thus the implant is not anhydrous. The fact that one component of the three component system may be anhydrous (e.g., a polymer) is not sufficient to render the present claims anticipated. The entire implant must be anhydrous.

Second, Ron fails to disclose a three component implant that is a solid structure. The “malleable implants” of Ron are “putty-like” (at col. 4, line 66) and putty-like materials are not solid structures as recited in the pending claims and described throughout Applicant’s specification as having a certain geometry. Indeed, Ron describes that some of his implants may be used as a percutaneous injection, necessarily rendering them capable of movement, *see* col. 6, line 5. The fact that one component of the three component system may be a solid (e.g. a polymer) is not sufficient to render the present claims anticipated. The entire implant must be a solid structure.

The implants of Ron are neither anhydrous nor solid structures, and therefore, claims 10, 13, and 18 are not anticipated thereby. Furthermore, Ron fails to suggest or even disclose why an implant that is an anhydrous solid structure may even be desirable. There are other differences between Ron and the claimed invention as well.

For example, Ron fails to disclose an implant that releases a therapeutically active agent “within a therapeutic dosage which does not vary by more than 100% for a period of at least about 3 days after implantation,” as required by claim 10 and claims 13 and 18, which depend thereon. Ron further fails to suggest why such a limitation may even be desirable. Accordingly, the rejections under 35 U.S.C §102(e) are improper and should be withdrawn.

New claims 34-43 have been added. Extensive support for these claims is provided variously throughout the specification. Support for claim 34 may be found, for example, on page 6, line 20 through page 7, line 2. Support for claim 35 may be found, for example, on page 10, line 12 through page 11, line 4. Support for claim 36 may be found, for example, on page 8,

lines 11-13. Support for claim 37 may be found, for example, on page 9, lines 11-15. Support for claim 38 may be found, for example, on page 4, lines 20-22. Support for claim 39 may be found, for example, on page 6, line 20 through page 7, line 2. Support for claims 40-43 may be found, for example, on page 12, lines 13-21. No new matter has been added.

Independent claims 34 and 39, from which the remaining newly added claims depend, recite an implant that is among other things an anhydrous solid structure. For all of the foregoing reasons, these claims are neither anticipated, nor made obvious by Ron.

Allowable Subject Matter

Claims 19, 20, 22-25, 28, 29, and 15-17

The Office Action notes that claims 19, 20, 22-25, 28, and 29 are allowed and that claims 15-17 have been objected to as being dependent upon a rejected base claim. While Applicants note that claims 15-17 would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims, Applicants have not amended these claims. Instead, Applicants submit that in view of the above Amendments and Remarks, all claims are allowable.

Conclusion

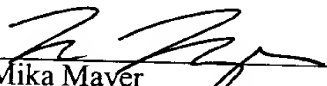
Applicants have responded to each matter of substance raised in the Office Action and submit that the case is in condition for allowance. If the Examiner has any requests, questions, or suggestions, or believes that a phone call may help expedite the prosecution of this case, he is invited to contact Applicants' agent at the number listed below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 440882001201. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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By:


Mika Mayer
Registration No. 47,777

Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018
Telephone: (650) 813-4298
Facsimile: (650) 494-0792

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

New claims 34-43 have been added.